Notice of Allowability	Application No.	Applicant(s)	
	09/457,771	EMANUELE ET AL.	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D.	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *10/16/06*.

2. ☒ The allowed claim(s) is/are *1,22,23,37 and 38*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in telephone interviews with Zara Doddridge on 11/17/06 and 11/21/06.

IN THE CLAIMS:

In claim 22, substitute --triplex DNA forming oligonucleotides-- for "triplex DNA compounds", and --substitute nucleic acids-- for "RNA messages".

In claim 23, rewrite the last three lines of the claim as:

--wherein ~~the~~ one or more of the nucleic acid molecules ~~are~~ is a gene used for supplying to an animal with a defective copy of one of its genes a normal copy of that gene; and,

wherein ~~the~~ one or more of the nucleic acid molecules encodes a normal copy of the gene.--

IN THE SPECIFICATION:

The electronic file for this application contains an abstract, specification, and a 4 page set of claims submitted on 7/28/2000. These documents were not requested by the Examiner, and SHOULD NOT BE PRINTED. Note that at page 1, and at the paragraph bridging pages 21 and 22 of this specification, amendments intended for the

originally-filed specification were instead entered into the specification filed 7/28/2000. These amendments were made on 12/4/01 (i.e. amendment "D_1"), and on 7/18/03 (i.e. amendment "G_1"). These amendments should be entered into originally filed application as follows:

At page 1, line 1 of the specification enter the following:

--The present application is a continuation of U.S. Patent Application Serial No. 09/104,088, filed June 24, 1998, abandoned, which is a continuation in part of U.S. Patent Application Serial No. 08/926,297, filed September 5, 1997, abandoned, which is a continuation of U.S. Patent application Serial No. 08/725,842, filed September 30, 1996, abandoned, which is a continuation of U.S. Patent Application Serial No. 08/138,271, filed October 15, 1993, abandoned.--

Replace the paragraph bridging pages 20 and 21 with the following:

--Briefly, phosphorothioate or methylphosphonate derivatives of a sequence complimentary to regions of the *art/trs* genes of HIV having the sequence 5'-TCGTCGCTGTCTCG-3' (SEQ ID NO: 1) are prepared according to the method of Matsukura et al. Three hundred milligrams (300 mg) of CRL-8131 is added to 10 ml of 0.9% NaCl and the mixture is solubilized by storage at temperatures of 2-4°C, until a clear solution is formed. The desired antisense oligonucleotide subsequently is mixed with the copolymer solution to provide a concentration effective in inhibiting viral activity when administered to a patient infected with the HIV virus. Generally the effective amount of antisense compound will be such that the final concentration in the blood is

in the range of 1μM to 100 μM, although other effective amounts of antisense compounds outside this range may be found for specific antisense compounds. One skilled in the art can readily test the relative effectiveness of any particular antisense oligonucleotide according to the *in vivo* test of Matsukura et al. --

IN THE ABSTRACT:

Please substitute the following abstract:

--The present invention relates to compositions and methods for delivery of antisense oligonucleotides or other nucleic acid sequences. The present invention comprises a delivery composition comprising an administerable admixture of an effective amount of a nucleic acid sequence and an effective amount of a surface active nonionic block copolymer having the following general formula:

$$HO(C_2H_40)_b(C_3H_6O)_a(C_2H_40)_bH$$

wherein a is an integer such that the hydrophobe represented by (C_3H_60) has a molecular weight between approximately 750 and approximately 15,000, preferably between approximately 2250 and approximately 15,000, more preferably between approximately 3250 and approximately 15,000, and b is an integer such that the hydrophile portion represented by (C2H40) constitutes approximately 1% to approximately 50% by weight of the compound, preferably approximately 5% to approximately 25%.--

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, J. Douglas Schultz, can be reached at (571) 272-0763. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Richard Schnizer, Ph.D.
Primary Examiner
Art Unit 1635